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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,604	03/08/2004	Richard S. Bein	355492-2971	1765

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
01/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,604	BEIN ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8 and 10-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-8 and 10-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed on 09/26/2008. Upon entering the amendment, claims 1, 4-7, 10-11 and 13-15 are amended. Claims 2-3 are cancelled. Accordingly, claims 1, 4-8 and 10-16 are pending and presented for examination.

Response to Arguments

2. Applicant arguments filed on 09/26/2008 with respect to claims are fully considered but they are not persuasive. Previous rejections that are not reiterated herein are withdrawn. However, the 102(e) rejection of Whalen et al (US 2002/0090339 A1) and Patterson et al (US 2004/0224864 A1) and 103(a) rejection of Whalen et al. (US 2002/0090339 A1) or Patterson et al. (US 2004/0224864 A1) in view of Evans et al. (US 5,695,480) is maintained and made **FINAL**.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 4-8 and 10-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Whalen et al. (US 2002/0090339 A1).

With respect to claims 1, 4-8 and 10-16, Whalen discloses a composition for embolizing blood vessels suited for treating vascular lesions via catheter deliver. And composition comprising: a biocompatible polymer at a concentration of from about 2 to about 50 weight percent; and a biocompatible contrast agent at a concentration of from about 10 to about 40 weight percent; and a biocompatible solvent from about 10 to about 88 weight percent wherein the weight percent of the biocompatible polymer, contrast agent and biocompatible solvent is based on the total weight of the complete composition (see abstract and para 0032-0035). And preferred biocompatible polymers include cellulose acetates, ethylene vinyl alcohol, copolymers, hydrogels, polyacrylonitrile, polyvinylacetate, cellulose acetate butyrate, nirtocellulose, copolymers of urethane/carbonate, copolymers of styrene/maleic acid, and mixtures thereof (see 0060). And water insoluble contrast agents include tantalum, tantalum oxide, and barium sulfate of particle size of about 10 microns or less and more preferably at from about 1 to about 5 microns (see para 0067 and 0078). And biocompatible solvent includes ethyl lactate, dimethylsulfoxide, ethanol, acetone and the like (see 0069). Therefore, all the critical elements as required by instant claims are taught by the cited reference and claims are anticipated.

Applicant arguments filed on 09/26/2008 have been fully considered but they are not persuasive.

Applicant asserts that Whalen et al. do not teach greater than 40 to 60 weight percent of water-insoluble, biocompatible contrast agent, as in the claimed invention. This argument is not persuasive since Whalen teaches a composition comprising biocompatible contrast agent at a concentration of from about 10 to about 40 weight percent. Since the concentration is from about 40 percent, it could be either 40 percent or grater than 40 percent. The amount of insoluble contrast agent concentration in a pharmaceutical composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of biocompatible contrast agent of active ingredient in order to achieve the desired results, such as for the preparation of compositions for embolizing blood vessels which are particularly suited for treating aneurysms, arteivenous malformations at high flow fistulas and embolizing blood vessels. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of biocompatible contrast agent concentration would have been obvious at the time of Applicant's invention.

And also applicant asserts that, Whalen et al. do not teach a ratio of biocompatible polymer to the water- insoluble biocompatible contrast agent to be 0.07 or greater.

This argument is not persuasive since this the ration of biocompatible polymer to the water-insoluble biocompatible contrast agent is with the broad scope of 0.07 or

grater when the biocompatible polymer from about 2 to about 50 weight percent; and a biocompatible contrast agent at a concentration of from about 10 to about 40 weight percent. Again this is an Optimizatoin of parameters and is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.,* 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1, 4-8 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whalen et al (US 2002/0090339 A1) and Patterson et al (US 2004/0224864 A1) in view of Evans et al (US 5,695,480).

Whalen et al. meets the claim limitations as described above.

With respect to claims 1, 4-8 and 10-16, Patterson discloses a sterile embolic composition suitable for embolizing a vascular site in a mammal. And composition comprising a biocompatible polymer from about 1 to about 12 weight percent; a biocompatible water insoluble contrast agent from about 20 to about 55 weight percent and a biocompatible solvent that is miscible in blood and other body fluids and serves to solubilize the biocompatible polymer (see abstract and para 0193).

Whalen and Patterson meets the claim limitation as discussed above, but fails to disclose explicitly the ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent is about 0.070 or greater.

Evans discloses compositions comprising biocompatible polymer from about 2.5 to about 8.0 weight, biocompatible contrast agent from about 10 to 40 weight and biocompatible solvent such as DMSO from about 52 to about 87.5 weight (see col. 3 lines 32-43). The teachings of Evan et al. provides a motivation and expectation of success by using the ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent is about 0.0625 in embolic composition comprising similar component used in overlapping range of concentrations as those claimed in the instant application.

It would have been obvious tone of ordinary skill in the art at the time the instant invention was made to combine the teachings of Whalen et al. or Patterson et al. and Evans et al. to make an embolic composition comprising the desired ration of biocompatible polymer to the water-insoluble biocompatible contrast agent. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention was

made to generate a composition comprising a non-reactive biocompatible composition, a theological modified a c biocompatible polymer to contrast agent ratio because the cited references and applicant disclose compositions comprising such components.

One would have been motivated to do so, with reasonable expectation of success because it is always desirable to have extended therapeutic modalities to improve patient's compliance by enhancing patient satisfaction and increasing the selection option. The techniques and skills required for making such substitution is conventional knowledge or well within the skills of ordinary artisan as evidenced by these references cited.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01 (a).

Applicant arguments filed on 10/26/2008 have been fully considered but they are not persuasive.

Applicant asserts that compositions of Patterson et al. are entirely different from the composition of instant claims. The composition of Patterson et al. is directed to a sterilized embolic composition comprising a hydroxyl-containing rheological modifier in an effective amount to impart shear thinning, pseudo elastic properties to the composition. This argument is not persuasive since, Patterson reference is combined for its teaches of knowledge in the art to provide improved procedures, in preparing embolic compositions suitable to embolize a vascular site for the purpose of treating

one or more conditions such as aneursym, an arteriovenous fistulae and the like. And in one embodiment, the sterilized embolic composition comprises a water insoluble, biocompatible polymer, a biocompatible solvent which dissolves the biocompatible polymer in the amounts employed and a visualizing effective amount of a contrast agent as recited in instant claims. And preferably, Patterson's composition, in the absence of a rheological modifiers, has viscosity of at least 500 cP at 37 °C would obviously provide improved viscous compositions used to embolize aneursyms as well as the lower viscosity compositions more typically employed in the treatment of an AVM and the like.

Applicant also asserts that Evans do not teach greater than 40 to 60 weight percent of the biocompatible contrast agent as and also do not specifically teach a ratio of biocompatible polymer to the water-insoluble biocompatible contrast agent of about 0.0625.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. *See In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir.1986). In this case, the Evans reference is relied upon to show that it is known in the art to prepare compositions for embolizing blood vessels which are particularly suited for treating vascular lesions. And composition comprises biocompatible polymer from about 2.5 to about 8.0 weight percent; water insoluble biocompatible contrast agents from about 10 to about 40 weight percent and biocompatible solvent from about 52 to about 87.5 weight percent. (If calculate the ration of biocompatible polymer to biocompatible

contrast agent would be within the limits as claimed). Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller,* 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955). Furthermore, the claims differ from the reference by reciting ratio of biocompatible polymer to water insoluble biocompatible contrast agents of the embolic composition. However, the preparation of pharmaceutical composition having various amounts of the active ingredient is within the level of skill of one having ordinary skill in the art at the time of the invention. It has been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell,* 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

Conclusion

1. No claims are allowed at this time.

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr